No. 52586-1-II

COURT OF APPEALS OF THE STATE OF WASHINGTON
DIVISION II

PHYLLIS COOLEN as Personal Representative of the Estate of PATRICK COOLEN, and Individually as Surviving Spouse;

Appellant,

v.

GROUP HEALTH OPTIONS, INC., a for profit Washington Corporation doing business in Thurston County; GROUP HEALTH COOPERATIVE, a Washington business entity doing business in Thurston County; GROUP HEALTH OF WASHINGTON, a Washington business entity doing business in Thurston County, JOHN DOES 1-3, providers of health care services in Thurston County, jointly and severally;

Respondents.

APPELLANT'S OPENING BRIEF

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I. INTRODUCTION

Patrick Coolen died of prostate cancer. GH failed to exercise reasonable care to periodically monitor and review the competency of its health care providers who practice medicine at GH on issues of PSA testing and documentation. GH claims that its policies are not policies, but rather are "guidelines" that need not be followed. And based on that assertion, GH failed to exercise reasonable care to adopt policies and procedures for health care provided to its patients. GH also failed to provide shared-decision making with Mr. Coolen and did not inform him of important procedures (PSA testing and then biopsy) that could have been performed as part of the workup leading to a diagnosis of prostate cancer.

The evidence in this case, and the law, supported Coolen's corporate negligence, shared decision-making and informed consent causes of action. Yet the Court took away those causes of action and failed to instruct the jury as to those matters. This was reversible error.

II. ASSIGNMENTS OF ERROR

Appellant seeks review by the Washington State Court of Appeals, Division II, of the trial court's orders and decisions as follows:

1. Excluding the introduction of any evidence with respect to lack of informed consent, and removing Plaintiff's informed

consent cause of action;

2. Failing to instruct the jury on informed consent;

3. Removing Plaintiff's shared decision-making cause of action;

4. Failing to instruct the jury on shared decision-making;

5. Removing Plaintiff's corporate negligence cause of action;

6. Failing to instruct the jury on corporate negligence;

Each of the trial court's rulings constitute reversible error.

III. ISSUES PERTAINING TO ASSIGNMENTS OF ERROR

1. Did the Superior Court err by excluding the Plaintiff from introducing any evidence of Defendant's failure to provide Decedent Patrick Coolen informed consent? YES.

2. Did the Superior Court err by removing Plaintiff's cause of action for informed consent at trial? YES.

3, Did the Superior Court err by failing to instruct the jury on informed consent? YES.

4. Did the Superior Court err by removing the Plaintiff's shared decision-making cause of action at trial? YES.

5. Did the Superior Court err by failing to instruct the jury on shared decision-making? YES.

6. Did the Superior Court err by removing Plaintiff's corporate negligence cause of action at trial? YES.

7. Did the Superior Court err by failing to instruct the jury on corporate negligence? YES.

IV. STATEMENT OF FACTS

1. Informed Consent:

A process for diagnosing prostate cancer is to conduct a prostate specific antigen (PSA) test and then a biopsy. Conducting a PSA test is the first step to ruling out prostate cancer – as you don't biopsy without a PSA. *VRP 181.*

Prostate specific antigen is protein made by cells that line the prostate. The PSA is made by these cells, and it leaks a particular protein into the blood. *VRP 129.*

A PSA test is a simple blood test that can pick up if PSA is leaking into the blood. *VRP 129.* If the PSA level is elevated, it can only mean one out of three things: (1) enlarged prostate; (2) inflamed prostate; (3) prostate cancer. *id.* Dr. Bretan, a medical expert who testified at trial in this case, testified: "It's a very simple, quick test." and "So we are fortunate that we have a simple screening for a life-threatening cancer." *VRP 129-130.*

At trial, Group Health ("GH") testified via its speaking agent Matthew Handley, MD. *VRP 451.*

GH testified that the harm of a PSA test is trivial and that there is very little harm in doing a digital rectal exam *and* a PSA test. *VRP 491; 506.*

GH's own policy (GH claims it's a discretionary "guideline") ask that

the PSA test to screen to prostate cancer be offered to patients and that if the patient declines, that the GH practitioner document that. *VRP 118.*

Trial Exhibit 1 was a GHC medical record pertaining to Patrick Coolen dated March 25, 2009. *CP 2297.* Dr. Bretan was asked about Exhibit 1 and he testified: "Well, the paragraph describes about screening, but it doesn't give the answer about what the patient says to that, whether it is a "yes" or a "no" or an understanding. So that's just an informational paragraph, and it's inadequately -- or it's inadequate to stand alone." *VRP 131.*

On September 13, 2010, Mr. Coolen presented to GH with complaints of a few months of urinary frequency/urge, some urethral discomfort and an urge to urinate about every hour while awake. *VRP 132.* He was found to have an engorged prostate at this visit. *id.* Mr. Coolen's condition was diagnosable as benign prostate hyperplasia, BPH – enlargement of the cells and the whole prostate. *VRP133.* Dr. Bretan was asked: "And so in 2010, the diagnosis was made for benign prostatic hypertrophy or hyperplasia?" and he answered: "That is correct." *VRP 133.*

From 2010 (after the diagnosis of enlarged prostate on September 13, 2010) to 2014, GH never put benign prostatic hyperplasia ("BPH") in the problem list or in any of the records. *VRP 252-253.* Dr. Staben was asked if

it is the patient's responsibility or the physician's responsibility to look at the problem list and make inquiry. *VRP 262.* Dr. Staben answered: "Well, the problem list is part of the physician's records. So the patient's not going to have anything -- you know, they're not going to have access to that." *Id.*

One action GH could and should have taken in the presence of these urinary tract findings and the enlarged prostate was to screen for prostate cancer if necessary. *VRP 133-134.* Dr. Bretan testified that was not done.

Dr. Bretan testified that Mr. Coolen had classic prostate irritation and deserved treatment **and diagnosis and follow-up**. *VRP 134.* Dr. Bretan was then asked: "And so to make a complete diagnosis, what is required?" and he laid out what could have been done: "As I said, you can try medications. If they work, it may be - - it may support your initial diagnosis of prostate problems. So that - - that would be the minimum. The minimum would be trial of medications **and follow-up.** The other issue simultaneously, because it's only a blood test, would be **prostate cancer screening**. You do that simultaneously. And those are two separate issues, one on the benign part of the prostate that the patient's already coming in, there's nothing loss to screen for cancer simultaneously." [bold emph added]. *VRP 134-135.*

Dr. Bretan testified that a PSA test "is far more sensitive and accurate" - comparing it to the less sensitive and accurate digital rectal

examination. *VRP 138.* Dr. Bretan also testified "So the reason to do prostate screening is to pick up those high-grade cancers that are going to kill you, very similar to the high-grade cancer Mr. Coolen had." *VRP 138.*

High-grade prostate cancer that is encapsulated in the prostate is, per Dr. Bretan's expert opinion at trial, "absolutely" survivable. *VRP 136.* Dr. Bretan's testimony established that Mr. Coolen had prostate symptoms and prostate disease and was "not an average person." *VRP 151.*

Dr. Jonathan Staben also testified as a medical expert at trial in this case. Dr. Staben opined that the standard of care for **working up** this problem would be to do a PSA test. *VRP 269.* Dr. Staben also testified that "[. . .] if you had a discussion here on this visit that said "I recommend a PSA" and the patient declined, then that's one acceptable way to comply with the standard of care. But that **- - that wasn't done here**. No. There was **no discussion** documented that a PSA was ordered **or even discussed with the patient**." [bold emph added]. *VRP 269-270.*

Dr. Staben testified about the failure of GH to discuss with Mr. Coolen the potential for his having cancerous tissue as part of the enlargement of the prostate: "[. . .] you've done a workup on this patient that included a urine test and an STD test on a 60-year-old male, and you've diagnosed them as having a benign tissue, and there's **no discussion** there of

the potential for it being a - - for having cancerous tissue as part of the enlargement of the prostate - - [. . .]" *VRP 270.* PA Rogers should have ordered a PSA test on this date. VRP 269.

Mr. Coolen was left in the dark. He was not informed about important procedures (PSA testing and then biopsy) that could have been performed as part of the workup leading to a diagnosis of prostate cancer. Rather than inform Mr. Coolen about alternative procedures that could conclusively diagnose prostate cancer or rule out prostate cancer (PSA testing then biopsy), Mr. Coolen was not so informed, but was instead lead to believe that his urinary problems were benign.

Testifying about the September 10, 2013 GH visit, Dr. Staben testified: "So that person is going to leave that office visit thinking that their urinary problems are caused by alcohol, caffeine, and a benign enlargement of their prostate. And so that's what they're going to go home with. And they're not going to go home with the fact that **this could be cancer**, because that -- that was not documented on that visit **or discussed.**" [bold emph added]. *VRP 272-273.*

Regarding this September 13, 2010 GH visit, Dr. Staben further testified: "That discussion of the possibility of it could be cancer or that there's further workup needed wasn't done." *VRP 273.*

In December, 2010, Patrick Coolen presented to GH, and there was evidence at that time that he had a prostate disease. *VRP 120.* Dr. Bretan testified:

> There -- there was evidence at that time that the patient had a prostate disease. The most common is enlargement of the prostate and secondary symptoms from that. But we don't know – because the PSA was not performed at that time, the screening for prostate cancer which can occur simultaneously with benign diseases of the prostate, we don't know if the PSA at that time was starting to rise.

VRP 120. GH did not perform a PSA at that time. *id.*

Dr. Bretan testified: "In my own experience and all of the urologists that I have talked to and all of the cancer screening lectures that I have talked to, this is the way urologists pick up localized prostate cancer, **by having a discussion, ordering the PSA** in this setting, **in this exact same setting.**" [bold emph added]. *VRP 121.*

Dr. Bretan opined that if GHC had given Patrick Coolen PSA testing in 2010, that would have "absolutely" provided a basis for further evaluation between 2010 and 2014. *VRP 121.*

Mr. Coolen was a higher risk patient, given his abnormal digital rectal exam and other urilogical conditions. Dr. Bretan was asked: "In 2010, based on the abnormal digital rectal exam, the urethral pain, the urgency, and the hourly urination, was Patrick Coolen an average risk patient?" and he

answered: "No. He's higher than average risk." *VRP 214.*

Dr. Staben was asked: "At any time from September of 2010 up through 2014, did you see any discussion in the records of Group Health advising him that he was at high risk of prostate cancer?" and he answered: "I don't recall seeing that discussion was ever done with the patient." *VRP 304-305.*

Dr. Bretan was asked: "There was discussion about cancer screening being done in 2003 and 2006 and 2009. If it wasn't documented, what was discussed? And if it wasn't documented that the patient actually agreed or disagreed, does that meet the standard of care with respect to documentation of cancer screening being done with that patient?" and he answered:

> No, it does not. Because when you're talking about the cancer that killed Mr. Coolen, you need to document that, because essentially, it is a life or death decision. And if it is not documented, then that could lead to a huge conflict in the future. So they ask that it be documented **if the patient opts, for whatever reason, but understands the consequences, that they document those reasons.** And **those were never documented**, and **the test was never performed.**

[bold emph added]. *VRP 118-119.* GHC admitted, through its speaking agent's testimony, that "The decision of the patient should be documented." *VRP 452.* GHC's speaking agent also admitted that during his residency training, Group Health taught in its residency: if it isn't documented, it wasn't done. *VRP 451.*

Dr. Bretan was asked: "And so looking at the record now in hindsight, will we ever know if Patrick Coolen was even offered PSA testing?" and Dr. Bretan answered:

> That's the problem. We do not know. All we know is that the test was not done. And we also know that the guidelines were violated, **because they weren't documented on why the patient declined.** [. . .]

[bold emph added]. *VRP 119.*

Dr. Staben was asked in this case: "Did you have any sense, in reviewing the records from 2010 up through 2014, whether there was a fair and balanced presentation of the risks and benefits of cancer screening to Patrick Coolen?" and he answered: "I don't think there's any discussion of that during those visits." *VRP 267.*

Dr. Bretan opined that in 2010, if Patrick Coolen had a prostate cancer, which Dr. Bretan believes more likely than not he did, it would have been contained to the prostate. *VRP184.*

Dr. Bretan was asked: "So Dr. Bretan, in your opinion, based on reasonable medical probability, if Patrick Coolen had received a PSA test in 2009 or 2010 or 2011, what would the outcome have been?" *VRP143.* Dr. Bretan answered: "Again, more likely than not, we'd pick up - - you would have a biopsy and we would make that diagnosis and we would offer him surgery, radiation, or both. [. . .]" *VRP 143.*

Dr. Bretan testified: "The [GHC] guidelines are well written, and the guidelines ask that the PSA test to screen for prostate cancer be offered to patients. And if it -- if the patient declines, the guidelines ask the practitioner of Group Health to document that. **It doesn't appear that any of those things happened at a time when the disease was confined to the prostate and the patient had no symptoms, thus a very curable state if it was found at that time.**" [bold emph added]. *VRP 118.*

Dr. Bretan was asked if the prostate cancer had been caught because of an elevated PSA in 2009 or in 2010, what would he expect the survival to be for Patrick Coolen, and he answered in pertinent part: "The data shows, as well as my personal data, that high-grade cancers, when picked up early, confined to the prostate is very curable." *VRP 139-140*

GHC had policies (which GHC claimed were discretionary guidelines). GH claimed it did not have policies (but rather guidelines) because this is an area of healthcare provider discretion. However, in written discovery responses, GH referred to these as "policies". *VRP1348-1349.*

Dr. Bretan testified that the guidelines are well written, and they ask that the PSA test to screen for prostate cancer be offered to patients, and if the patient declines, the guidelines ask the practitioner of Group Health to document that. *VRP trial volume 1:118.* Dr. Bretan testified that "It doesn't

appear that any of those things happened at a time when the disease was confined to the prostate and the patient had no symptoms, thus a very curable state if it was found at that time." *Id.*

Dr. Staben testified that "But I would say that he - - he never had a PSA done, ever." *VRP 263.*

The Court incorrectly excluded Coolen's informed consent cause of action and failed to instruct the jury on informed consent. *VRP 9.10.18, 59-60; VRP 830; CP 2275-2296.* The Court applied the *Backlund* rule to this case, even though this case falls directly within the exception set forth in *Backlund v. Univ. of Washington,* 137 Wash. 2d 651, 659, 975 P.2d 950 (1999). The *Baklund* rule is that a provider cannot be liable for failure to inform in a misdiagnosis case. But that rule is not controlling here, as it is not on point in this case. This is a case where GH failed to inform Mr. Coolen as to alternative treatments/procedures (PSA testing followed by biopsy) that could have been taken to rule in or out prostate cancer. And the facts of this case drive directly through the opening left by the Supreme Court in *Backlund* to maintain *both* a failure to diagnose cause of action (malpractice) and an informed consent cause of action.

The *Backlund* case states: "There are situations where a provider could be liable for failure to inform without negligence. The most obvious

example would be a provider who knows about two alternative treatments but informs the patient of only one treatment, which is subsequently performed perfectly." *Id at* 619.

Other examples of situations not excluded by the *Backlund* rule are illustrated in *Gates v. Jensen,* 92 Wash. 2d 246, 595 P.2d 919, (1979). "Important decisions must frequently be made in many non-treatment situations in which medical care is given, including procedures **leading to** a diagnosis, [. . .]." [bold emph added]. *Gates v. Jenseon,* at 250-251. "These decisions must all be taken with the full knowledge and participation of the patient." *Id at 251.*

The erred when it excluded the informed consent cause of action and failed to instruct the jury on informed consent.

The Court also erred by failing to instruct the jury on shared decision making. *See CP 2275-2296; VRP 1394-1395.* The evidence in the record supported the giving of the instruction. For example, Coolen's treating GH provider Dr. Kendra Smith was asked: "In 2010, what was the policy with respect to prostate cancer screening?" and she answered: "Shared decision-making." *VRP 331.* She was then asked, "And when you had shared decision-making, what did that require?" and she answered: "Discussion with the patient regarding the risk/benefits of prostate cancer

screening." *VRP* 332. Dr. Smith also testified that it was a requirement that the screening discussion be documented. *VRP 332.* She also testified that it was a requirement that the man's decision about whether to be screened or not had to be documented. *VRP 332.* GH's speaking agent even testified: "The whole way in which we've constructed our work around prostate cancer, it is - - is to involve a man in shared decision-making so that they can decide what they'd like to do." *VRP 455.*

The lack of shared decision-making by GH with Mr. Coolen as to PSA testing is (as shown above) substantial. Dr. Staben's testimony established that shared-decision making involves a discussion about the risks and benefits of prostate cancer screening. *VRP 268.*

Referring to PSA testing, GH admitted that every man should make the decision for themselves. *VRP 485.* GH was then asked: "And that assumes unbiased shared decision-making." *VRP 485.* GH then answered: "Correct." *VRP 485.* GH admitted that it believes that shared decision-making in prostate cancer screening improves outcome. *VRP 487.*

Dr. Smith, a GH provider, was asked: "Looking at Exhibit Number 1, [the March 25, 2009 GH record] down under the "pertinent positive exam findings," do you see that paragraph starting with the "natural history"? and then she was asked "Do you see anything that said that Patrick Coolen

accepted or rejected cancer screening?" and she answered: "I don't see - - I don't see that. [. . .]" *VRP 333-334.* Dr. Smith was also asked (pertaining to the September 10, 2013 GH record): "And in her record that we just reviewed, is there anything about a PSA test anywhere in that document?" And she answered: "I do not see PSA listed." *VRP 336.* Dr. Smith also admitted that she does not dispute that shared decision-making has to be documented. *VRP 336.*

On cross examination GH's attorney asked Dr. Bretan: "Well, there were multiple discussions over the three - - the preceding decade about prostate cancer with Mr. Coolen; isn't that correct?" And Dr. Bretan answered:

> As we had outlined before, the discussion is in a paragraph form. There is **no affirmative understanding**, which is usually the description of the shared decision-making, **of understanding informed consent issues**. That's why we had discussed that aspect of that paragraph before. So you may be alluding to the issues about prostate cancer screening, but as in 2010, I believe, there's a paragraph, a digital rectal exam, **no PSA screening nor -- nor a reason not to do PSA screening**, which is part of the Group Health guidelines.

[bold emph added]. *VRP 165.* RCW 7.70.060(3) states: As used in this section, "shared decision making" means a process in which the physician or other health care practitioner discusses with the patient or his or her representative the information specified in subsection (2) of this section with

the use of a patient decision aid and the patient shares with the provider such relevant personal information as might make one treatment or side effect more or less tolerable than others." *RCW 7.70.060(3).* Subsection (2) of RCW 7.70.060 states:

> If a patient while legally competent, or his or her representative if he or she is not competent, signs an acknowledgment of shared decision making as described in this section, such acknowledgment shall constitute prima facie evidence that the patient gave his or her informed consent to the treatment administered and the patient has the burden of rebutting this by clear and convincing evidence. An acknowledgment of shared decision making shall include:
>
> (a) A statement that the patient, or his or her representative, and the health care provider have engaged in shared decision making as an alternative means of meeting the informed consent requirements set forth by laws, accreditation standards, and other mandates;
>
> (b) A brief description of the services that the patient and provider jointly have agreed will be furnished;
>
> (c) A brief description of the patient decision aid or aids that have been used by the patient and provider to address the needs for (I) high-quality, up-to-date information about the condition, including risk and benefits of available options and, if appropriate, a discussion of the limits of scientific knowledge about outcomes; (ii) values clarification to help patients sort out their values and preferences; and (iii) guidance or coaching in deliberation, designed to improve the patient's involvement in the decision process;
>
> (d) A statement that the patient or his or her representative understands: The risk or seriousness of the disease or condition to be prevented or treated; the available treatment alternatives, including nontreatment; and the risks, benefits, and uncertainties of the treatment alternatives, including

nontreatment; and

> (e) A statement certifying that the patient or his or her representative has had the opportunity to ask the provider questions, and to have any questions answered to the patient's satisfaction, and indicating the patient's intent to receive the identified services.

The Court erred when it excluded Coolen's share decision-making cause of action and failed to instruct the jury as to shared decision-making. *See Coolen's proposed shared decision-making instruction at CP 2204-2205.*

2. Corporate Negligence:

After Mr. Coolen's case-in-chief, GH brought a CR 50 motion for directed verdict on Mr. Coolen's corporate negligence claim. *CP 1949-1960. VRP 811.* Having heard the evidence presented in Mr. Coolen's case-in-chief, the Court denied GH's motion. *VRP 833-834.*

But on the last day of trial, the Court took the corporate negligence cause of action away from Mr. Coolen and did not give a corporate negligence instruction to the jury. *VRP 1361-1368; CP 2275-2296.*

2(a) Failure to exercise reasonable care to adopt policies and procedures:

Under the doctrine of corporate negligence, GH had a duty to exercise reasonable care to adopt policies and procedures for health care provided to its patients. *See WPI 105.02.02.*

At trial, GH was asked point blank: "Does Group Health have any

men's health policies for prostate cancer" and GHC answered: "We do not" *VRP 577.*

2(b). Failure to exercise reasonable care to periodically monitor and review the competency of all health care providers who practice medicine at GH.

Under the doctrine of corporate negligence, GH had a duty to exercise reasonable care to periodically monitor and review the competency of all care providers who practice medicine at GH. *See WPI 105.02.02.*

At trial, GH was asked: "So you just said, as I heard you, that you have training for your physicians, but you don't put in place any system, any audit, any control that would audit whether they're actually giving that information to the patient.", and GH answered: "That is correct." *VRP 535-536.*

Dr. Bretan was asked: "What should have occurred in the presence of these urinary tract findings and this enlarged prostate?" and Dr. Bretan answered: "Well, when one presents with a chief complaint and you are able to make a diagnosis, then **you would treat it.** And there are good prostate medicines out there, and **you would follow it.** The alternative is to send them to a specialist such as me." [emph added]. *VRP 133.* Dr. Bretan was asked if doing a urine test that came back normal and doing a test for sexually transmitted disease that came back normal be enough in the presence of those symptoms, and he answered: "Absolutely not. Those are two separate

entities. Sexual transmitted disease has nothing to do with pure prostate issues in this age group. So the age and demographics of the group are different. This is classic prostate irritation and deserves treatment and diagnosis and **follow-up.**" [bold emph added]. *VRP 133.*

GH provider Dr. Kendra Smith was asked if before Mr. Coolen's visit to her on November 2, 2013, she was aware that Coolen had been diagnosed with benign hyperplasia in September of 2010, three years earlier. *VRP 326.* Dr. Smith answered: "No, I was not aware." *VRP 326.* She admitted that she never saw "benign prostatic hyperplasia" when she looked at those records three years after the diagnosis on November 22, 2013. *VRP 327.*

At trial GH was asked: "And so you talk about the training that you give, but you don't do a thing to see if it's actually being implemented by your providers for prostate cancer screening. You don't audit. You don't check. You don't review their records. You don't look it for performance purposes. You don't even know what they say about prostate cancer screening in the patient's records, do you?" *VRP 560.* GH answered: "We do not audit the records. *VRP 560.*

3. Coolen's death:

Mr. Coolen died of prostate cancer at age 66. *VRP 608.* Dr. Bretan testified that "All I know is, more likely than not, greater than 50 percent

chance of having it confined in 2010. Somewhere between 2010 that - - we know aggressive cancers grow. And then it basically grew out of the prostate and became metastatic, as we saw it in 2014. We know how that curve looks. It's not a straight line. It actually takes off at the very end. So you can go back on most cancers that go this way and trace it back one, possibly two years. The earliest that you could estimate that he could have still been saved would possibly be early 2013, late 2012." *VRP 142-143.*

By 2014, when his cancer was diagnosed (by a non-GH facility) the cat was out of the bag, and he was in a very dire situation. Dr. Bretan was asked: "Because of the time in which the cancer was diagnosed at a 701 and metastatic in 2014, were his options for treatment limited?" and he answered: "The cat's out of the bag. At his point, we are looking at a very dire situation." *VRP 143.*

V. ARGUMENT

"A trial court's decision to give a jury instruction is reviewed de novo if based upon a matter of law, or for abuse of discretion if based upon a matter of fact." *Kappelman v. Lutz,* 167 Wash. 2d 1, 6, 217 P.3d 286 (2009).

"In evaluating whether the evidence is substantial enough to support a defendant's proposed instruction, the trial court must interpret it most strongly in his favor and must not weigh the proof, which is an exclusive jury

function." *State v. Douglas,* 128 Wash. App. 555, 561–62, 116 P.3d 1012, 1016 (2005).

Jury instructions are sufficient when they allow counsel to argue their theory of the case, are not misleading, and when read as a whole properly inform the trier of fact of the applicable law. *id at 562.*

"When reviewing a motion for judgment as a matter of law (formerly judgment n.o.v.), this court applies the same standard of review as the trial court. *Guijosa v. Wal-Mart Stores, Inc.,* 101 Wash. App. 777, 795–96, 6 P.3d 583, 593 (2000), aff'd, 144 Wash. 2d 907, 32 P.3d 250 (2001).

In the present case, the Courts' failure to give corporate negligence, shared decision-making and informed consent instructions prevented Coolen from arguing those theories of the case. The Court misapplied the law and disregarded or failed to appreciate substantial evidence supporting these legal theories.

1. Corporate Negligence

Corporate negligence has its own jury instruction, specifically, WPI 105.02.02. That instruction provides:

> A hospital owes an independent duty of care to its patients. This includes the duty to:
>
> 1. [exercise reasonable care to grant and renew staff privileges so as to permit only competent physicians and surgeons to use its facilities.]

2. [exercise reasonable care to periodically monitor and review the competency of all health care providers who practice medicine at the hospital.]

3. [exercise reasonable care to intervene in the treatment of a patient at the hospital under the care of an independent physician if one of its officers, employees, or agents becomes aware of obvious negligence.]

4. [exercise reasonable care to adopt policies and procedures for health care provided to its patients.]

"Reasonable care" in this instruction means that degree of skill, care, and learning expected of a reasonably prudent hospital in the State of Washington acting in the same or similar circumstances and at the same time of the care or treatment in question. Failure to exercise such skill, care, and learning is negligence.

The degree of care actually practiced by hospitals is evidence of what is reasonably prudent. However, this evidence alone is not conclusive on the issue and should be considered by you along with any other evidence bearing on the question.

[numbers 1 through 4 added for ease of reference hereafter]. WPI 105.02.02 Hospital Responsibility-Corporate Negligence, 6th Ed. "One commentary finds four such duties owed by a hospital under the doctrine of corporate negligence: (1) to use reasonable care in the maintenance of buildings and grounds for the protection of the hospital's invitees; (2) to furnish the patient supplies and equipment free of defects; (3) to select its employees with reasonable care; and (4) to supervise all persons who practice medicine within its walls." *Douglas v. Freeman,* 117 Wash. 2d 242, 248, 814 P.2d

1160 (1991).

"Judgment as a matter of law is appropriate **only** when no competent and substantial evidence exists to support a verdict." [bold emph added]. *Paetsch v. Spokane Dermatology Clinic, P.S.,* 182 Wash. 2d 842, 848, 348 P.3d 389 (2015).

In the present case, GH moved for directed verdict on corporate negligence. The Court denied GH's motion for directed verdict, which meant that there existed competent evidence or a reasonable inference to sustain a verdict on corporate negligence in favor of Coolen.

In GH's' motion, and specifically with respect to GH's duty to exercise reasonable care to periodically monitor and review the competency of all health care providers who practice medicine at GH, GH argued: "Plaintiff introduced no evidence whatsoever concerning the vetting and/or hiring of any of Mr. Coolen's medical providers during the period of the alleged negligence." *CP 1954.*

This argument ignores the actual duty, which is to exercise reasonable care to **monitor** and **review** the competency of all health care providers who practice medicine at the hospital.

With respect to GH's duty to exercise reasonable care to adopt policies and procedures for health care provided to its patients, GH argued

in its motion: "Plaintiff has not identified any mandatory policy or rule that Group Health employees/agents were required to follow." *CP 1955.*

The Court stated in pertinent part:

> With respect to the issue of corporate negligence, the court finds that there are reasonable inferences to support corporate negligence under the argument in a light most favorable to the nonmoving party; that **the corporation did not exercise reasonable care to review the competency of healthcare providers and failed to exercise reasonable care to adopt procedures for healthcare.**

VRP, volume 4:833-834. However, on the last day of trial, the Court informed the parties that "the court is not going to issue instructions on corporate negligence." *VRP 1360-1361.* The Court then stated, "I know this will be a surprise to the parties, [. . .]" *VRP 1361.*

The Court then provided his rationale for this decision. As to duty number two of corporate negligence (fail to exercise reasonable care to monitor and review) the Court informed the parties that: "[The Court] had an opportunity to review the transcript of the testimony of Dr. Handley in its entirety. And Dr. Handley's testimony on that issue was limited to his testimony regarding, Group Health did not monitor its healthcare providers insofar as their PSA policies, in other words, how often and under what circumstances." *VRP 1362.*

The Court informed the parties that the case law that he researched

with respect to the duty to supervise healthcare providers within their walls (duty two of corporate negligence) lead the court to conclude that that duty applies "only in the instances when the hospital is aware of obvious negligence." *VRP 1364.*

The Court appears to have co-mingled portions of separate corporate negligence duties, specifically he included the "aware of obvious negligence" provision of duty three into duty two, the duty to exercise reasonable care to monitor and review. *See WPI 150.0202.*

Referring to the *Pedroza v. Bryant,* 101 Wash. 2d 226, 677 P.2d 166 (1984), in 2017 Supreme Court stated: "There, we observed that in addition to the physicians themselves, "[h]ospitals are also in a superior position to monitor and control physician performance."" *Taylor v. Intuitive Surgical, Inc.,* 187 Wash. 2d 743, 756, 389 P.3d 517 (2017) quoting *Pedroza, supra at 231.*

GH had a duty to exercise reasonable care to periodically monitor and review the competency of all health care providers who practice medicine at the hospital (duty two) and contrary to the Court's ruling, this duty does **not** apply only in the instance when the hospital is aware of obvious negligence. The Court committed reversible error when it injected a qualification into this duty that the law does not provide.

Substantively, GHC breached this duty. *See VRP 534-536; 560; 569,* GHC was asked on direct examination: "If most men who have prostate cancer are never going to be found unless you do digital rectal exams and PSA testing, why isn't Group Health doing that?" and GHC answered: "We are not going to test people against their will. We are going to give them that information, and if they want to be tested, we are totally on board with that." *VRP 534-535.*

GHC was then asked: "What alerts or what audits of your providers does Group Health as a corporation do and have in place to ensure that the providers are having these types of conversations that you've been talking about, that we've been talking about with this jury, and then follow up on it"" and GHC answered in pertinent part: "We do not audit the charts or track the use of PSA testing at a population level." *Id at 535.*

GHC was next asked: "So you just said, as I heard you, that you have training for your physicians, but you don't put in place any system, any audit, any control that would audit whether they're actually giving that information to the patient.", and GHC answered: "That is correct." *Id at 535-536.*

GHC was also asked: "And so you talk about the training that you give, but you don't do a thing to see if it's actually being implemented by your providers for prostate cancer screening. You don't audit. You don't

check. You don't review their records. You don't look it [sic] for performance purposes. You don't even know what they say about prostate cancer screening in the patient's records, do you"? and GHC answered: "We do not audit the records." *Id at 560.* GHC again admitted that GHC "did no audits" of the patient records. *id at 569.*

In the pattern instruction on corporate negligence, "reasonable care" means that degree of skill, care, and learning expected of a **reasonably prudent** hospital in the State of Washington acting in the same or similar circumstances. *See WPI 105.02.02.*

In this case, there was testimony from medical expert Peter Bretan as to what Kaiser did regarding monitoring (GH was not yet Kaiser when Coolen was treated at GH). And what Kaiser did was screen and implement an electronic medical record **tracking of their physicians.** *VRP 222.*

The Court committed reversible error when it removed Mr. Coolen's corporate negligence cause of action and failed to instruct the jury on corporate negligence – despite overwhelming evidence from GH's speaking agent as to GH's failure to put in place any system, any audit, any control that would audit whether the providers are actually giving to the patient the life-or-death information that prostate cancer in most men is never going to be found unless a digital rectal *and* PSA test is done.

The Court's rationale for not instructing the jury on corporate negligence as it pertains to duty four (the duty to exercise reasonable care to adopt policies and procedures for health care provided to its patients) was also error.

The Court relied on RCW 70.41.030, and determined that it referred only to the "construction and plans for construction of medical facilities." *VRP 1366.* But that is incorrect.

RCW 70.41.030 also refers to "operation of hospitals" and "adequate care and treatment of patients":

> The department shall establish and adopt such minimum standards and rules pertaining to the construction, maintenance, **and operation of hospitals**, and rescind, amend, or modify such rules from time to time, as are necessary in the public interest, and particularly for the establishment and maintenance of standards of hospitalization required for the safe and **adequate care and treatment of patients.** [. . .]

[bold emph added]. *RCW 70.41.030 in pertinent part.* Plaintiff's counsel informed the Court of this. *VRP 1399-1400.*

The Court also relied on WAC 246-320 and stated that "It is clear to the court that the purpose behind the Washington Administrative Code [WAC 246-320-001 to 246-320-600] is for the Department of Social and Health Services' ability to make certain that healthcare providers are compliant with regulations contained within that code that have nothing to do

whatsoever with establishing policies, programs, requirements of healthcare portion of hospital care." *VRP 1367.* The Court stated:

> There's a long list there, none of which, arguably, would have anything to do whatsoever with the responsibility of a hospitals's or in this case Group Health, obligation to establish policies and procedures with respect to a particular area of care, in this case, of course, prostate screening.
>
> Upon reflection, that makes sense to the court, because the prong at issue refers to -- the prong, as it relates to corporate negligence, refers to the obligation to exercise reasonable care to adopt policies and procedures for healthcare provided to its patients. That, in the court's opinion now and the court's conclusion, is limited to the areas or subjects or topics set forth in the Washington Administrative Code just referenced by the court and RCW 7.41 [sic]. It has nothing to do whatsoever with establishment or the requirement of a hospital to adopt policies with respect to a particular methodology of providing healthcare.
>
> So the court believes that it would be error for this court to instruct the jury on corporate negligence.

id at 1367-1368. The Court also misapplied WAC 246-320 as part of his basis for not giving a corporate negligence instruction to the jury. WAC 246-320 **supports** Plaintiff's corporate negligence action – it even has a section entitled "PATIENT CARE". Within that section is WAC 246-320-226, entitled "**Patient care services.**", which includes the "use of preestablished patient care guidelines or protocols" – which is on point with this case. WAC 246-320-226 states in pertinent part:

> This section guides the development of a plan for patient care.

> This is accomplished by supervising staff, establishing, monitoring, and enforcing policies and procedures that define and outline the use of materials, resources, and promote the delivery of care.
> Hospitals must:
> (1) [. . .]
> (2) [. . .]
> (3) **Adopt, implement**, review and revise **patient care policies and procedures** designed to guide staff that address:
> (a) [. . .]
> (b) [. . .]
> (c) [. . .]
> (d) [. . .]
> (e) [. . .]
> (f) [. . .]
> (g) **Use of preestablished patient care guidelines or protocols.** When used, these must be documented in the medical record and be preapproved or authenticated by an authorized practitioner;
>
> [. . .]

[bold emph added]. *WAC 246-320-226 in pertinent part.* Coolen's counsel informed the Court of what WAC 246-320-226(g) stated and that it "seems to be right on point with our particular case." *VRP 1400-1401.*

The Court committed reversible error by failing to instruct the jury on corporate negligence, based on the incorrect determination that WAC 246-320 and RCW 70.41 "has nothing to do whatsoever with establishment or the requirement of a hospital to adopt policies with respect to a particular methodology of providing healthcare."

Substantively, GH breached its duty exercise reasonable care to adopt

policies and procedures as required by law – if you believe GH's trial testimony (opposed to their written discovery responses). In written discovery responses, GH referred to these as "policies". *VRP 1348-1349.*

Yet believing that it would benefit at trial by claiming these policies were guidelines that were not required to be followed (opposed to policies that were required to be followed), GH changed its position and made a concerted effort at trial to claim that its policies were "guidelines", not policies. *See e.g. VRP 3:455.* GH testified that guidelines are "information to use rather than rules to be followed." *VRP 575.* GH was asked: "Does Group Health have any men's health policies for prostate cancer" and GHC answered bluntly: "We do not" *VRP 577.*

Yet the Court effectively shielded GH from liability for failing to exercise reasonable care to adopt policies and procedures – despite GH essentially admitting to this breach. GH was shielded because the Court, based on a flawed interpretation of RCW 70.41 and WAC 246-320 did not instruct the jury on corporate negligence.

"Clearly, as argued by the plaintiff, it appears that the hospital by statute has a duty of care for the safety of its patients, independent of the care that may be chargeable to a patient's attending physician." *Osborn v. Pub. Hosp. Dist. I, Grant Cty.,* 80 Wash. 2d 201, 205, 492 P.2d 1025 (1972).

This trial contained evidence of GHC's breach of two separate duties, each constituting corporate negligence. The Court erred by removing Plaintiff's corporate negligence cause of action and by not instructing the jury on corporate negligence. Even if the jury determined there was an absence of negligence by GHC under vicarious liability for its doctors, the jury still could have found GHC liable under the doctrine of corporate negligence. "It is well settled that under the doctrine of corporate negligence, a hospital can be held liable for its own negligence in the absence of any negligence on the part of the treating physician." *Douglas v. Freeman,* 117 Wash. 2d 242, 252, 814 P.2d 1160, 1166 (1991)

2. Informed Consent / Shared Decision-Making

"The doctrine of informed consent has been distinguished from malpractice as applying to fundamentally different situations." *Gomez v. Sauerwein,* 180 Wash. 2d 610, 618, 331 P.3d 19 (2014).

The proposition that a provider cannot be liable for failure to inform in a misdiagnosis case is known as the *Backlund* rule. *See Gomez v. Sauerwein,* 180 Wash. 2d 610, 618, 331 P.3d 19 (2014). The *Backlund* rule is not absolute. "There are situations where a provider could be liable for failure to inform without negligence. The most obvious example would be a provider who knows about two alternative treatments but informs the patient

of only one treatment, which is subsequently performed perfectly." *Id at* 619.

Gates v. Jensen, 92 Wash. 2d 246, 595 P.2d 919, (1979) is an example of an instance where the duty to inform arises during the diagnostic process. "Under *Gates,* there may be instances where the duty to inform arises during the diagnostic process, [. . .]." *Gomez v. Sauerwein, supra* at 623. "The determining factor is whether the process of diagnosis presents an informed decision for the patient to make about his or her care." *id.*

The present case fits drives directly on the road laid out by the Supreme Court in *Backlund* that is not blocked by the "*Backlund* rule". In *Gates v. Jensen, supra,* the first question was whether the doctrine of informed consent requires a physician to inform a patient of a bodily abnormality discovered during a routine examination and of diagnostic procedures which may be taken to determine the significance of that abnormality.

In May 1972 Elisabeth Gates consulted Dr. James Hargiss, an ophthalmologist with the respondent Eye Clinic of Seattle. She complained of difficulty in focusing, blurring, and gaps in her vision. *Gates v. Jensen, supra, at 247.* Mrs. Gates was 54 years old at the time and had a severe myopia which doubled her risk of glaucoma. *id.* Dr. Hargiss took eye

pressure readings with a Schiotz tonometer and found the pressure in each eye registered 23.8 on the Goldman scale. *id.* This reading indicated Mrs. Gates was in the borderline area for glaucoma. id. Dr. Hargiss then examined Mrs. Gates' optic nerves with a direct ophthalmoscope to determine whether the discs, or surfaces, of the nerves showed the exacerbated "cupping" which is characteristic of glaucoma. *id* There was evidence at trial that observation of the nerve discs in Mrs. Gates' case was particularly difficult with the direct ophthalmoscope when the pupils were not dilated. *id.* Nonetheless Dr. Hargiss did not dilate Mrs. Gates' pupils. *id.* He could see no evidence of abnormality and made no further tests for glaucoma. In response to Mrs. Gates' inquiry about the pressure test, he said he had checked for glaucoma but found everything all right. *id at 247-248.* He diagnosed her problem as difficulties with the contact lenses she wore and treated her accordingly. *id at 248.*

The Supreme Court noted that "The significant facts in this case are that Dr. Hargiss neither told Mrs. Gates he had found high pressure in both eyes which put her in a borderline glaucoma area, nor that her risk of glaucoma was increased considerably by this high pressure and her myopia. Furthermore, Dr. Hargiss had available to him two additional diagnostic tests for glaucoma which are simple, inexpensive, and risk free." *Id.*

Over the next 2 years Mrs. Gates revisited the clinic 12 times complaining of blurring, fog, and gaps in her vision, as well as loss in visual acuity. *id.* Shortly after her first visit Dr. Hargiss made another pressure reading and found pressures in both eyes to be within the high range of normal. *id.* There was evidence at trial that in the early stages of glaucoma pressures can vary drastically from normal to positive glaucoma readings within a 24-hour period. *id.*

In April 1974 doctors at the clinic diagnosed Mrs. Gates as having open angle glaucoma. *id.*

In *Gates,* it was petitioners' contention that the doctors had a duty to tell her (1) that she had high pressures in her eyes, (2) that she was in a high risk group for glaucoma, and (3) that there were alternative diagnostic procedures available to determine conclusively whether she had glaucoma – so she could make an informed choice about treatments she would undergo, and that if she had been informed of these facts she would have requested the additional tests and glaucoma would have been discovered. *id at 250.*

It was respondents' contention that the doctrine of informed consent does not apply to questions of appropriate diagnostic procedures and the requested instruction was properly rejected. *id.* The Supreme Court disagreed. *id.*

"The patient's right to know is not confined to the choice of treatment once a disease is present and has been conclusively diagnosed." *Id.*

"Important decisions must frequently be made in many non-treatment situations in which medical care is given, including procedures **leading to** a diagnosis, [. . .]." [bold emph added]. *Gates v. Jenseon, supra at 250-251.*

"These decisions must all be taken with the full knowledge and participation of the patient." *Id at 251.*

And so the question becomes, what is the physician's duty? The Supreme Court answers this question, stating: "The physician's duty is to tell the patient what he or she needs to know in order to make them." *Id.*

As was evident by the evidence at trial, and set forth above in the Facts section, Mr. Coolen was not informed of what he needed to know in order to make important decisions in the process of diagnosing his disease– a disease that ultimately killed him.

Patrick Coolen had **abnormal conditions** relative to his prostate in his body. Patrick Coolen had the **presence of a high risk** of prostate cancer. There were **diagnostic procedures that existed** to conclusively determine the presence or absence of prostate cancer (i.e. PSA test followed by a biopsy). *See VRP 118-119, 120-121, 131, 133-134, 143, 214, 267, 269-270, 272-273, 304-305.*

The Supreme Court was clear: "The existence of an abnormal condition in one's body, the presence of a high risk of disease, and the existence of alternative diagnostic procedures to conclusively determine the presence or absence of that disease are **all facts which a patient must know in order to make an informed decision** on the course which future medical care will take." [emph added]. *Gates v. Jensen, supra* at 251.

"The facts which must be disclosed are all those facts the physician knows or should know which the patient needs in order to make the decision. To require less would be to deprive the patient of the capacity to choose the course his or her life will take." *Id at 251.*

It was error when the Court took away from Coolen the informed consent cause of action and failed to instruct the jury on informed consent. The jury's verdict on the medical negligence case does not render this error harmless. "Informed consent allows a patient to recover damages from a physician even though the medical diagnosis or treatment was not negligent." *Backlund v. Univ. of Washington,* 137 Wash. 2d 651, 659, 975 P.2d 950 (1999).

Similarly, the Court erred by failing to instruct the jury shared decision-making. RCW 7.70.060 defines shared decision-making. GH testified that the whole way in which it constructed its work around prostate

cancer is to involve a man in shared decision-making so that he can decide what he'd like to do. *See VRP 455.*

According to GH provider Kendra Smith, shared decision-making required: "Discussion with the patient regarding the risk/benefits of prostate cancer screening." *VRP 332.* Dr. Smith also testified that it was a requirement that the screening discussion be documented and that the man's decision about whether to be screened or not had to be documented. *VRP 332.* Yet, as shown in the facts above, GH failed to provide shared decision-making with Mr. Coolen.

Dr. Staben was asked in this case: "Did you have any sense, in reviewing the records from 2010 up through 2014, whether there was a fair and balanced presentation of the risks and benefits of cancer screening to Patrick Coolen?" and he answered: "I don't think there's any discussion of that during those visits." *VRP 267.*

Dr. Bretan opined that in 2010, if Patrick Coolen had a prostate cancer, which Dr. Bretan believes more likely than not he did, it would have been contained to the prostate. *VRP184.*

3. Attorney fees:

RCW 7.70.070 states:

> The court shall, in any action under this chapter, determine the reasonableness of each party's attorneys fees. The court

shall take into consideration the following:

(1) The time and labor required, the novelty and difficulty of the questions involved, and the skill requisite to perform the legal service properly;

(2) The likelihood, if apparent to the client, that the acceptance of the particular employment will preclude other employment by the lawyer;

(3) The fee customarily charged in the locality for similar legal services;

(4) The amount involved and the results obtained;

(5) The time limitations imposed by the client or by the circumstances;

(6) The nature and length of the professional relationship with the client;

(7) The experience, reputation, and ability of the lawyer or lawyers performing the services;

(8) Whether the fee is fixed or contingent.

The Personal Representative requests attorney's fees on appeal under RAP 18.1 and RCW 7.70.070. *Morinaga v. Vue,* 85 Wash.App. 822, 935 P.2d 637 (1997).

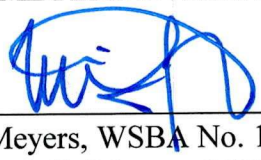
VI. CONCLUSION

The Court's decision to prevent Mr. Coolen from taking his informed consent, shared decision-making and corporate negligence causes of action to the jury – and failing to instruct the jury on those matters, was reversible

error. Coolen respectfully requests that this Court reverse those decisions and order a new trial.

DATED: April 5, 2019.

RON MEYERS & ASSOCIATES PLLC



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No. **52586-1-II**

WASHINGTON STATE COURT OF APPEALS
DIVISION II

PHYLLIS COOLEN as Personal Representative of the Estate of PATRICK COOLEN, and Individually as Surviving Spouse; Appellant, v. GROUP HEALTH OPTIONS, INC., a for profit Washington Corporation doing business in Thurston County; GROUP HEALTH COOPERATIVE, a Washington business entity doing business in Thurston County; GROUP HEALTH OF WASHINGTON, a Washington business entity doing business in Thurston County, JOHN and/or JANE DOES 1-3, providers of health care services in Thurston County; and BUSINESS ENTITIES 1-3, providers of health care services in Thurston County, jointly and severally; Respondents.	**DECLARATION OF SERVICE OF APPELLANT'S OPENING BRIEF**

I declare under penalty of perjury under the laws of the State of Washington that on the date stated below I caused the documents referenced below to be served in the manners indicated below on the following:

DOCUMENTS:
1. Appellant's Opening Brief, and
2. This Declaration of Service.

ORIGINALS TO:

David C. Ponzoha, Court Clerk
Washington State Court of Appeals Division II

[✓] Via Hand Delivery

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DATED this 5th day of April, 2019, at Olympia, Washington.

Mindy Leach, Litigation Paralegal